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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,284	02/15/2002	Kazuaki Sasaki	H&A-107	9039
7590 07/01/2005 MATTINGLY, STANGER & MALUR, P.C. 1800 Diagonal Road, Suite 370 Alexandria, VA 22314			EXAMINER MANTIS MERCADER, ELENI M	
			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/075,284

Applicant(s)

SASAKI ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/12/05</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Response to Arguments***

Applicant's arguments filed on 4/12/2005 have been fully considered but they are not persuasive. The added limitations of "coagulated" are recitations of intended use and therefore do not limit the structure of the apparatus. The ultrasonic transducer is capable of coagulating tissue. The structure or properties of therapy that bring about the end result of coagulation must be claimed if that is Applicant's intent. With respect to the continuous insonation mode, Applicant's attention is respectfully redirected to Rosenchein et al.'558, col. 3, lines 62-67 and col. 4, lines 1-34 which clearly teaches this limitation. For at least these reasons the rejection is maintained and made Final.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenchein et al. US Patent No. 6,113,558, of record in view of Ueberle et al. US Patent No. 4,819,621, hereinafter Ueberle et al.'621.

Rosenchein et al.'558 teach setting a therapeutic transducer to operate at a continuous mode insonation in order to maintain cavitation at a region of interest to be treated (see col. 3, lines 62-67 and col. 4, lines 1-34) while the operator is allowed to watch or listen (see col. 5,

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lines 4-19) from a display and/or a microphone and determine whether cavitation is occurring under the desired conditions (col. 7, lines 60-67 and col. 8, lines 1-31). The ultrasonic transducer is capable of coagulating tissue. The microphone provides a detected audible sound, which is correlated with the occurrence of cavitation (col. 8, lines 18-31).

Rosenchein et al.'558 do not expressly teach a waveform analyzing unit which obtains a cross-correlation function between a waveform of the detected audible sound and a typical waveform of an audible sound previously obtained in a region to be treated as an indication of the occurrence of cavitation.

In the same field of endeavor, Ueberle et al.'621 teach a waveform analyzing unit which obtains a cross-correlation function between a waveform of the detected audible sound and a typical waveform of an audible sound previously obtained in a region to be treated as an indication of the occurrence of cavitation (see col. 1, lines 55- col. 3, line 7; referring to a test signal or typical waveform being cross-correlated with the reception signal or the detected audible signal in order to determine the occurrence of cavitation by waveform comparison).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Rosenchein et al.'558 and incorporated the teachings of Ueberle et al.'621 in utilizing the waveform analyzing unit as an alternative functional equivalent of detecting the occurrence of cavitation. In other words, rather than detecting just a sound as taught by Rosenchein et al.'558, detecting a comparative sound which nonetheless functions in the same manner of providing an indication that cavitation is occurring.

Furthermore, Ueberle et al.'621 teaches that the detection from the waveform analyzing unit can be linked to a control signal which can be further utilized (see col. 4, lines 31-44).

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Therefore, it would also have been obvious to one skilled in the art at the time that the invention was made to have utilized the control signal to stop, alter or continue treatment based on the treatment protocol of interest. Rosenchein et al.'558's protocol teaches the maintenance of cavitation (see col. 3, lines 62-67 and col. 4, lines 1-34). Therefore, the control signal as taught by Ueberle et al.'621 could be utilized to maintain cavitation treatment.

Finally, use of FFT analysis would have been an alternative waveform analysis for detection of a comparative signal in order to identify the occurrence of cavitation. Therefore, the FFT analysis is a functional equivalent to the waveform analysis as taught by Ueberle et al.'621.

### *Conclusion*

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM